

# EXHIBIT 2

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA )

Ex Rel )

VEN-A-CARE OF THE )  
FLORIDA KEYS, INC. )  
a Florida Corporation, )  
by and through its principal )  
officers and directors, )  
ZACHARY T. BENTLEY, )  
T. MARK JONES, )  
JOHN M. LOCKWOOD AND )  
LUIS E. COBO )

Plaintiff, )

v. )

[REDACTED] )  
[REDACTED] )  
[REDACTED] )  
DEY, INC.; )  
[REDACTED] )  
[REDACTED] )  
[REDACTED] )

Defendants. )

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CIVIL ACTION NO. 00CV10698MLW

FILED IN CAMERA AND UNDER SEAL

COMPLAINT

For Money Damages and Civil  
Penalties Under the False Claims Act

31 U.S.C. §§3729-3732

COMPLAINT  
FOR MONEY DAMAGES AND CIVIL PENALTIES UNDER THE FALSE  
CLAIMS ACT 31 U.S.C. §§3729-3732

COMES NOW, the UNITED STATES OF AMERICA ("UNITED STATES" or "GOVERNMENT"), by and through VEN-A-CARE OF THE FLORIDA KEYS, INC. ("VEN-A-CARE" or "the Relator"), and its principal officers and directors, ZACHARY T. BENTLEY, T. MARK JONES, JOHN M. LOCKWOOD and LUIS E. COBO and by and through the undersigned attorneys on behalf of the UNITED STATES and on the Relator's own behalf and

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brings this action against \_\_\_\_\_, DEY  
INC., \_\_\_\_\_

\_\_\_\_\_, (sometimes referred to collectively as "DEFENDANTS"), for money damages and civil penalties arising out of the DEFENDANTS' violations of the Federal False Claims Act, 31 U.S.C., §§3729-3732 from on or about April 7, 1994, to the present date.

**SECTION NO. 1  
SUMMARY OF THE ACTION**

**DRUG MANUFACTURERS' FALSE PRICE REPRESENTATIONS  
INVOLVING RETAIL PHARMACIES**

1. This is an action for damages, treble damages, civil penalties and costs against the DEFENDANTS for violation of the False Claims Act as set out in Counts I through VII, pages 49 through 59. The DEFENDANTS falsely represented the prices that they charged wholesalers for certain of their generic prescription drugs (hereinafter sometimes referred to as the "specified drugs") in order to cause various State Medicaid Programs to pay claims in excessive amounts. More than half of the amounts paid consisted of federal funds from which the States were required to pay claims based upon the drug's Estimated Acquisition Cost ("EAC") to the pharmacy submitting the claim. 42 CFR §447.331.

2. The DEFENDANTS knew that each of the States' Medicaid Programs had implemented a mechanism to estimate acquisition cost of prescription drugs to the pharmacy and that most states, including but not limited to Alabama, Colorado, Florida, Maryland, Massachusetts, Ohio, Rhode Island, and Texas (hereinafter sometimes referred to as "WAC STATES") relied on the DEFENDANTS' representation of the prices they charged

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wholesalers for the specified drugs. The DEFENDANTS' false price representations were made directly to the WAC STATES and other states by the DEFENDANTS and through First Data Bank ("FDB"), the company that assembles drug price data for the State Medicaid Programs.

3. The DEFENDANTS each knew that the WAC STATES' Medicaid Programs relied on the DEFENDANTS' representations of the prices that the DEFENDANTS charged wholesalers in setting the amount to be reimbursed to the pharmacy. This information was used to determine the Wholesaler Acquisition Cost ("WAC") for the specified drugs to which a percentage was added to estimate the acquisition cost of the pharmacy purchasing from the wholesaler. The DEFENDANTS reported truthful prices for most drugs and the States' Medicaid Programs were thus able to accurately estimate acquisition costs when paying claims. In the case of the specified drugs, however, the DEFENDANTS falsely inflated their reports of the prices charged to wholesalers so that Medicaid pharmacy providers would be paid excessive amounts and thus choose the specified drugs over competing generic versions.

4. The DEFENDANTS each benefitted from their false price representations because they were able to create a "Spread" between the inflated acquisition cost that they caused the States to calculate and the reasonable and realistic estimate of acquisition cost that the States intended to base payments of claims on. The "Spread" thus constituted an unlawful financial inducement arranged by the DEFENDANTS to cause their Medicaid provider customers to order their specified drugs instead of their competitors'. The

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DEFENDANTS thus duped the WAC STATES' and other states' Medicaid Programs into paying claims for the specified drugs at inflated amounts in order to increase the DEFENDANTS' sales. The DEFENDANTS, in effect, lied about the price of their specified drugs in order to cause the States to expend Medicaid Program dollars to unwittingly fund unlawful kickbacks to Medicaid providers.

5. The DEFENDANTS' wrongful exploitation of the States' Medicaid Programs caused the UNITED STATES to incur single damages in excess of Ten Million Dollars for which the United States and States' Medicaid Programs are entitled to recover treble damages plus up to Ten Thousand Dollars per false claim, interest, costs and attorneys' fees.

**SECTION NO. 2  
THE PARTIES**

6. The Plaintiff in this action is the UNITED STATES. At all times material to this civil action, the United States Department of Health and Human Services ("HHS") and the Health Care Financing Administration ("HCFA"), were charged with administering the Medicaid program.

7. The States of Alabama, Colorado, Florida, Maryland, Massachusetts, Ohio, Rhode Island and Texas and other States provided Medicaid benefits to qualified recipients which included payment of claims for the prescription drugs, specified herein, manufactured by the DEFENDANTS and relied upon the false price representations made by the DEFENDANTS in approving and paying claims. A significant part (a minimum of 50%) of said

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Medicaid reimbursement was paid from United States Government funds pursuant to 42 U.S.C. § 1396(b).

8. The Relator, VEN-A-CARE, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Relator's principal officers and directors include Zachary T. Bentley, T. Mark Jones, John M. Lockwood and Luis E. Cobo who are each citizens of the United States and reside in Key West, Florida. The Relator is a pharmacy providing prescription drugs and is a Florida Medicaid pharmacy provider. The Relator has direct and independent knowledge of the information and is the "original source" of the information on which these allegations are based within the meaning of 31 U.S.C. §3730(e)(4)(A) and (B). The Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1). The information upon which these allegations are based was voluntarily provided by the Relator to the Federal Government beginning on or before November 1996 and thereafter has been frequently supplemented by the Relator.

9. Ven-A-Care's principals were aware that Medicaid reimbursement for the drugs at issue was required by federal law to be based on an estimation of cost and not provide for windfall profits at the GOVERNMENTS' expense. Ven-A-Care attempted to alert the responsible state and federal government officials to the matters alleged herein; however, the government agencies lacked sufficient resources and expertise to adequately respond. Accordingly, the Relator commenced this action based upon its original source information.

10. [REDACTED]  
[REDACTED]

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[REDACTED]

11.

[REDACTED]

12. DEFENDANT, DEY, INC. f/k/a DEY LABORATORIES, INC. ("DEY"), is a corporation organized under the laws of Delaware with its principal offices in Napa, California. At all times material to this civil action, DEY has transacted business in the Federal Judicial District of Massachusetts by, including, but not limited to, selling directly or through wholesalers its specified prescription drugs in the District of Massachusetts knowing that the drugs would be supplied to Medicaid recipients and for which claims would be paid from Medicaid funds.

13.

[REDACTED]



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[REDACTED]

14. [REDACTED]

[REDACTED]

15. Any and all acts alleged herein to have been committed by any or all of the DEFENDANTS were committed by each Defendant's officers, directors, employees, or agents who at all times acted on behalf of their respective DEFENDANT.



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**SECTION NO. 3  
JURISDICTION & VENUE**

16. Jurisdiction is founded upon the Federal False Claims Act (the "Act"), 31 U.S.C. §3729-32, specifically 31 U.S.C. §3732, and also 28 U.S.C. §§1331, 1345.

17. The Federal False Claims Act reaches the type of fraudulent activity alleged herein in accordance with the express language of the Act as well as precedents arising from applications of the present Federal False Claims Act and earlier versions. See, United States v. Neifert-White Company, 390 U.S. 228; 88 S.Ct. 959 (1968). Specifically, the United States Supreme Court's application of the Act in Neifert-White applies to this case as follows:

A. ". . . the Act was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." 88 S.Ct., at 961.

B. The Act applies to the conduct of a manufacturer that supplies falsely inflated price information in support of a customer's claim. 88 S.Ct., at 960.

C. The Act applies even where the price information supplied by the DEFENDANTS is inflated by only approximately 25% over the truthful price. 88 S.Ct., at 960.

D. The Act applies even if the DEFENDANTS did not submit the false price information directly to the Government and even though the DEFENDANTS received no payment of funds from the Government.

E. The Act applies even though the inflated portion of the price was received by customers of the DEFENDANTS who are not parties to the case. 88 S.Ct., at 960.

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18. Venue in the District of Massachusetts is appropriate under 31 U.S.C. §3732(a) and sufficient contacts exist for jurisdiction in that each of the DEFENDANTS transacted business in the District of Massachusetts by selling directly or through wholesalers their specified prescription drugs in the District of Massachusetts which the respective DEFENDANTS knew would be supplied to Medicaid recipients and for which the DEFENDANTS knew that grossly excessive and unreasonable payments for claims would be made to the pharmacies by the STATES' Medicaid programs.

19. A copy of the Complaint and written disclosure of substantially all material evidence and information VEN-A-CARE possesses were served on the Government pursuant to Rule 4(i)(1)(A) and (B), Fed.R.Civ.P., prior to the filing of the initial Complaint in camera and under seal by delivering a copy of the summons, Complaint, material evidence and information to the United States Attorney for the District of Massachusetts and by sending a copy of the summons, Complaint, material evidence and information by certified mail to the Attorney General of the United States at Washington, District of Columbia.

20. The Relator alleges: (A) that no allegation or transaction of defrauding the United States was made prior to the filing of the Complaint in public disclosures regarding the subject matter herein against any of the DEFENDANTS; (B) that none of the DEFENDANTS was named in public disclosures made prior to the filing of the Complaint regarding the subject matter herein; and (C), if the Court makes a finding against the Relator as to the allegations set forth in (A) and/or (B), that the Relator has direct and independent knowledge of the information on which these allegations are based within the meaning of 31 U.S.C.

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§3730(e)(4)(A) and (B) and has voluntarily provided the information to the Government before filing the Complaint which is based on the information provided by the Relator to the Government and the Relator is the original source.

21. Federal Court jurisdiction also exists over this cause for reasons which include, but are not limited to, the following:

A) The RELATOR, due to its status as an industry insider, has acquired substantial information that is of significant value to the Government about the DEFENDANTS' false claims scheme and has provided said information to the Government in accordance with the False Claims Act.

B) The RELATOR has expended substantial time, money and resources, and has incurred substantial financial and other risks in reviewing its own information and in acquiring, analyzing and disclosing to the Government its information about the DEFENDANTS' false claims scheme, prior to commencing this action.

C) The remedies provided by the False Claims Act include, in part, an award to the RELATOR for providing to the Government the information about the DEFENDANTS' false claims scheme that is at issue in this action. In order to secure redress of its right to such award, the RELATOR has complied with the requirements of the False Claims Act that it initiate this action under seal and disclose all its information to the Government.

D) This False Claims Act case constitutes the only lawful mechanism whereby the RELATOR may receive redress in the form of compensation for providing

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information about the DEFENDANTS' false claims scheme and for assisting the Government in recovering amounts paid, multiple damages and penalties.

E) The False Claims Act provides a mechanism whereby the RELATOR may secure redress for its cause of action, to wit, its right to compensation for benefitting the Government through use of its information about the false claims scheme in the manner contemplated by the False Claims Act.

F) The RELATOR is also entitled, under the False Claims Act, to litigate the Government's right to damages and penalties, arising from the false claims scheme and has a stake in the outcome in that the RELATOR is entitled by the False Claims Act to share in any recovery secured by or on behalf of the Government.

G) The DEFENDANTS each possess a substantial interest in disproving the RELATOR'S allegations of violations of the False Claims Act and the RELATOR possesses a substantial interest in proving said allegations, as well as the investment of the RELATOR's costs and its overall compliance with the pre-filing and post filing procedural and jurisdictional provisions of the False Claims Act, because the determination of these issues under the False Claims Act will establish whether:

- (i) The DEFENDANTS violated the federal False Claims Act;
- (ii) The DEFENDANTS are liable for treble damages, penalties, costs, RELATOR's expenses and attorneys' fees.
- (iii) The RELATOR is entitled to redress in the form of compensation for providing its information about the false claims scheme to the

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Government and for assisting the Government in the manner required by the False Claims Act;

- (iv) The RELATOR is entitled to redress, on behalf of the Government, in the form of damages and penalties from the DEFENDANTS.
- (v) The RELATOR is entitled to redress in the form of its relator's share of the award of damages and penalties.
- (vi) The RELATOR is entitled to redress in the form of compensation for its expenses, incurrence of risk, and investment of time and resources in acquiring and providing to the Government its information about the false claims scheme.

H) In the event that the Government intervenes with respect to some or all of the RELATOR's allegations and claims, then the RELATOR is entitled to participate in the litigation to the extent and under the conditions specified in the False Claims Act and to further pursue redress in the form of its right to share in any award and receive compensation for its costs and expenses.

I) In the event that the Government does not intervene with respect to some or all of the RELATOR's allegations and claims, then the RELATOR's causes of action alleged herein are directed at further redress in that only by prevailing in litigation based on its information about the false claims scheme will the RELATOR be able to seek: redress in the form of deterrence of ongoing and future conduct injurious to the RELATOR; compensation



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for its information about the DEFENDANTS' false claims scheme; compensation for the assistance and benefit it provided to the Government; compensation for its expenses, risks and devotion of time and resources in acquiring and providing information to the Government; and compensation for establishing the DEFENDANTS' liability for damages and penalties.

**SECTION NO. 4  
BACKGROUND OF HOW UNITED STATES' MONIES  
ARE PAID FOR DRUG CLAIMS UNDER  
THE STATES' MEDICAID PROGRAMS**

22. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq.

23. Benefits for prescription drugs are optional but all states have opted to provide Medicaid drug reimbursement coverage.

24. The federal portion of States' Medicaid payments, the Federal Medical Assistance Percentage ("FMAP") is based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. By way of example, the FMAP contributed by the United States in 1995 was: Alabama 70.45%, Colorado 53.10%, Florida 56.28%, Maryland 50.0%, Massachusetts 50.0%, Ohio 60.69%, Rhode Island 55.49% and Texas 63.31%.

25. The States, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage

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and payment of claims in order to qualify for federal funds for Medicaid expenditures. 42 U.S.C. §1396a(a)(30)(A).

26. State Health Plans must, in part, provide for payment of claims for prescription drugs pursuant to a formula approved by the Secretary of HHS which determines the maximum allowable claim amount for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement based upon an estimation of the pharmacy's acquisition cost of the drug plus a reasonable dispensing fee. 42 CFR 447.331.

27. Drug manufacturers, including the DEFENDANTS, the Medicare and the Medicaid Programs, drug price and cost reporting services, hospitals, pharmacies, physicians, wholesalers, third party payors (e.g. insurance companies), and others involved in the health care industry, communicate about prescription drug prices and costs by describing the price and cost with terms such as:

- a) Average Wholesale Price ("AWP")
- b) Wholesaler Acquisition Cost ("WAC")
- c) List Price
- d) Direct Price ("DP")
- e) Wholesale Net Price

28. HCFA has approved state plans whose methodology formulae for arriving at a pharmacy's estimated acquisition cost as required by 42 CFR 447.331 includes:

- a. discounting a percentage off of the AWP prices as computed by or collected by and published by First Data Bank;



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- b. adding a percentage to the WAC prices as computed by or collected by and published by First Data Bank ; and,
- c. the state of Texas which requires drug companies, including the DEFENDANTS, to certify directly in writing to the Texas vendor drug program their prices.

29. The HCFA approved State plans for the WAC States at issue are:

	<u>Drug</u>	<u>Dispensing Fee</u>
Alabama	WAC+9.2%	\$5.40
Colorado	lesser of AWP-10% or WAC+18%	\$4.08
Florida	WAC+7%	\$4.23
Maryland	WAC+10%	\$4.21
Massachusetts	WAC+10%	\$3.00
Ohio	WAC+11%	\$3.70
Rhode Island and	WAC+5%	\$2.85-\$3.40
Texas	direct certification of price by the drug companies	\$5.27 + 2%

30. The Texas Medicaid Program has gone to exceptional lengths to verify that drug manufacturers, including the DEFENDANTS, provide truthful price and cost information for reimbursement purposes. The Texas Medicaid authorities, acting pursuant to 25 Texas Administrative Code 35.801, required the DEFENDANTS to certify, in writing, the accuracy of their price and cost representations as a condition to their drugs being covered for

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reimbursement. The Relators' investigation has revealed that each of the DEFENDANTS, when responding to Texas, about their specified drugs, either affirmatively lied about their true prices, or omitted material information in order to mislead the Texas Medicaid officials.

30. The State of Texas pays reimbursement for drugs covered by its Vendor Drug Program at the lesser of the provider's usual and customary charge or Estimated Acquisition Cost ("EAC"). In Texas' Pharmacy Provider Handbook, EAC is defined as either the Wholesale Estimated Acquisition Cost ("WEAC") or the Direct Estimated Acquisition Cost ("DEAC"). WEAC is the estimated price paid by providers purchasing a drug from a wholesaler. DEAC is the estimated price paid by a provider purchasing the drug directly from the drug's manufacturer.

31. The State of Texas required the DEFENDANTS to complete a specific form regarding the prices of their drugs. Immediately before the required signature by the DEFENDANTS' representatives is the following language:

"I hereby certify that the information submitted is correct to the best of my knowledge... I also agree to inform the Texas Department of Health of any changes in.....price.....within fifteen (15) days of such change."

Attached hereto as Exhibit "1" is a true and correct copy of the current certification used by Texas Medicaid.

32. The Food and Drug Administration ("FDA") assigns National Drug Codes, ("NDC") numbers to identify each individual manufacturer and its drugs' strengths and sizes. NDC numbers are eleven digits, with the first five digits identifying the manufacturer or labeler, the next four digits identifying the product and the last two digits identifying the package size.

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33. First Data Bank ("FDB") is a nationally recognized company that specializes in collecting and publishing drug data including pricing. FDB provides prices and costs for approximately 80,000 different drugs, sizes and strengths expressed in terms of AWP and WAC through an electronic or automated service. More than 90% of the States' Medicaid Pharmacy Programs utilized the AWP and WACs as communicated by First Data Bank's automated services in determining reimbursement amounts for Medicaid prescription drug claims.

34. Pharmacies are required to utilize the FDA's NDC numbers when submitting claims for reimbursement for drugs to the States' Medicaid programs.

35. Congress has attempted to assist the States' Medicaid programs in limiting reimbursement amounts for certain generic prescription drugs to a reasonable estimate of acquisition cost by empowering the Health Care Financing Administration to set a Federal Upper Limit ("FUL") for drugs paid for by the Medicaid Programs. Under the plan, HCFA may impose a FUL on any generic drug pursuant to the following criteria :

a. All formulations of the drug must have been evaluated as therapeutically equivalent by the FDA.

b. There are at least three (3) companies that list the drugs in current published compendia with their cost and the drugs must be available for sale nationally.

c. HCFA then finds the least costly generic as listed in all available national compendia that can be purchased by pharmacies and multiplies this amount by 150%. This

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amount then becomes the FUL for all manufacturers' generic form of the drug or the maximum amount a State Medicaid Program can pay.

37. Pharmacies are reimbursed for prescription drugs by the States' Medicaid Programs at the lower of :

- i) the State's HCFA approved plan (i.e. Massachusetts' WAC+ 10%); or,
- ii) the pharmacies usual and customary charges to the general public ;or,
- iii) the Federal Upper Limit ("FUL") plus a reasonable professional or dispensing fee.

38. The vast majority of States award cost-reimbursement contracts to private companies to evaluate and process Medicaid recipients' claims for payment. The States refer to these contractors as fiscal agents.

39. Prescription drug claims are submitted in one of two ways. The first is by submitting to the fiscal agent or state agency a completed (hard copy) pharmacy claim form. The second is through an electronic claims filing procedure (on-line claims adjudication) whereby the same information required to be included on the hard copy is transmitted electronically to the Medicaid fiscal agent or state agency.

40. The majority of the DEFENDANTS' drugs, including the specified drugs at issue in this action, are distributed through drug wholesalers who resell and distribute the drugs to hospitals, pharmacies, physicians and clinics.

41. Four companies, McKesson Drug, Cardinal, Bergen Brunswig and Ameri-Source, comprise approximately eighty (80%) of the 53 billion dollar annual wholesale drug

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market. Wholesalers generally sell to any person or entity (i.e. pharmacies, physicians and hospitals) who can lawfully purchase prescription drugs.

42. Wholesalers purchase the specified drugs at prices that are unilaterally set and controlled by the DEFENDANTS. The wholesalers in turn add a percentage (commonly referred to as an “up-charge”) to the price that they pay the DEFENDANTS. The “up-charge” covers the wholesaler’s expenses such as warehousing, delivery, billing and collections and provides a profit. The percentage of up-charge is negotiated between the pharmacy and the wholesaler and is usually based of the pharmacy’s purchasing volume. By way of example, the Relator’s up-charge from McKesson is 6.5%

43. The DEFENDANTS also sell directly and indirectly to hospitals and retail pharmacies through group purchasing organizations (“GPO’s”) and buying groups. GPO’s and buying groups represent smaller providers and provide members with lower costs by negotiating prices for specific drugs from the manufacturers. The GPO or buying group member is able to purchase the drugs at the GPO’s or buying group’s negotiated price either directly from the manufacturer or from a wholesaler that has a “charge-back” agreement with the specific manufacturer.

44. The DEFENDANTS’ “charge-back” arrangements with wholesalers allows the DEFENDANTS to sell drugs, including some of the drugs at issue in this case, to the wholesalers at a fictitiously inflated price. When a wholesaler sells a drug who’s price has been negotiated with a GPO or buying group, the wholesaler is credited by the DEFENDANT for the difference between the false price and the true price to the DEFENDANTS’ customer



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plus the agreed “up charge” for the wholesaler. The “charge-back” scheme allows the DEFENDANTS to utilize the services of the wholesalers while establishing the retail prices for their drugs.

45. The “charge-back” scheme is illustrated by the following example of the drug,

\_\_\_\_\_, manufactured by DEFENDANT \_\_\_\_\_ and wholesaled through McKesson Drug Co. (“McKesson”):

a) McKesson’s March 2000 published wholesale price for \_\_\_\_\_, is \$29.48;

b) Ven-A-Care is a member of the Servall buying group. Servall is a McKesson sponsored buying group that is available to any retail pharmacy that purchases prescription drugs from McKesson;

c) Ven-A-Care’s Servall buying group’s price for \_\_\_\_\_, is \$7.93. Therefore, VAC can purchase a bottle of \_\_\_\_\_ from McKesson for \$8.45 which includes McKesson’s 6.5% up-charge to Ven-A-Care. This is \$21.03 less than McKesson purportedly paid DEFENDANT \_\_\_\_\_;

d) McKesson claims a “charge-back” from DEFENDANT \_\_\_\_\_ of \$21.55 which represents the difference in price from what McKesson paid (\$29.48) versus the price McKesson sold it to VAC (\$7.93), not including McKesson’s up-charge.

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46. In order to monitor the wholesalers' compliance, the DEFENDANTS require all drug wholesalers to periodically (generally quarterly) report back to the DEFENDANTS all prescription drug sales by NDC number, provider name and sales price.

47. A representative example of this practice was demonstrated when VAC was informed by a [REDACTED] sales representative that [REDACTED] and other drug manufacturers consider this information vital in determining how and where to market their prescription drugs. The [REDACTED] representative informed VAC that [REDACTED] prepared reports for every sales representative based on the information compiled from all wholesalers' reports and that the [REDACTED] report was broken down by postal zip code, provider, NDC number, quantity and sales prices.

48. First Data Bank receives and relies upon the drug manufacturers', including the DEFENDANTS', representations of their drug prices and costs including the prices at which the DEFENDANTS sell their drugs to wholesalers (WAC) in determining the drug pricing data that they report to the STATES.

49. The Relator's investigation has determined that the DEFENDANTS provide First Data Bank with either the WAC price of its drugs or instructions, if necessary, expressed in a manner that allows First Data Bank to establish the WAC.

50. During the time covered by this complaint, First Data Bank has defined WAC as "wholesaler acquisition cost" for a particular drug. A form entitled "New Product Submission Form" is provided by First Data Bank to drug manufacturers, including the DEFENDANTS, to transmit information, including their prices, to First Data Bank. The form



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permits drug manufacturers to submit prices expressed in terms of Wholesale (Distributor) Price, Direct Price and AWP Price. Attached hereto is true and exact copy of said form as Exhibit "2".











51. The Relator's information revealed that each of the DEFENDANTS had been the source of the price and cost information which was reported by First Data Bank to the STATES' Medicaid Programs at all times at issue in this action. The Relator reported its information to the Government, including specific identification of representatives of First Data Bank to whom such information was reported.











52. The States' Medicaid Programs also receive price and cost representations directly from the DEFENDANTS and use them to confirm the accuracy of price and cost in computing reimbursement amounts. Attached hereto as Composite Exhibit "3" are true and correct copies of price representations made by DEFENDANTS [REDACTED] to the State of Florida Medicaid Pharmacy Program on or about December 20, 1994 and September 26, 1994. Attached hereto as Exhibit "4" is a true and correct copy of price representations provided to Texas Medicaid by DEFENDANT [REDACTED] on or about March 6, 1997.










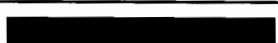
53. The importance that drug manufacturers represent truthful costs and prices and how these representations affect reimbursements is demonstrated by the following examples:

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54. The representations of drug prices made by the DEFENDANTS to First Data Bank and directly to the States' Medicaid Programs are material for the establishment of reasonable reimbursements to be made by the States' Medicaid Programs.

**SECTION NO. 5  
THE FALSE CLAIMS SCHEME**

**a.) A description of the False Claims Scheme.**

55. The DEFENDANTS are each liable under the False Claims Act because they caused the STATES' Medicaid Programs to pay claims for certain of their generic prescription drugs in exorbitant amounts, far in excess of the reasonable reimbursement permitted under the applicable statutes and regulations. The DEFENDANTS manufactured and/or distributed the specified prescription drugs in this action and sold the specified prescription drugs either directly to the pharmacies or indirectly through such intermediaries as wholesalers and group purchasing organizations. The false claims for excessive reimbursement were then submitted to the STATES' Medicaid Programs by the DEFENDANTS through their false price statements and by their customers (the pharmacies) who thereby received a windfall financial benefit in the amount by which the Governments' approved "reimbursement" exceeded a reasonable estimate of acquisition cost.

56. The DEFENDANTS also caused the submission of false claims by actively marketing their specified drugs to pharmacies by the use of financial inducements created by "the Spread" between the DEFENDANTS' true wholesale prices to the pharmacies and the STATES' Medicaid Programs reimbursements based on the DEFENDANTS' falsely inflated

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wholesale prices reported to the STATES' Medicaid Programs and their subcontractors. The financial inducements were in many cases enhanced by such things as free goods, discounts, and rebates.

57. The DEFENDANTS knew that the STATES' Medicaid Programs would not pay or approve claims for the specified drugs if it were disclosed to the STATES' Medicaid Programs that said claims were for amounts that included illegal remuneration prohibited by the anti-kick back statutes, 42 U.S.C. §1320a-7b(b)(2) and 1395nn(a)(1)(B).

58. The DEFENDANTS also knew that pharmacies, in presenting claims for the specified drugs to the STATES' Medicaid Programs, would not and did not disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2) and 1395 nn(a)(1)(B).

59. The claims in question are each false claims under the False Claims Act, in part, because they were each supported by and the payment amount determined due to the false and misleading price and cost information provided by the DEFENDANTS for the Government's use in connection with their respective specified drugs. The false and misleading representations of wholesale prices by the DEFENDANTS were material in that the information was used in setting the STATES' Medicaid reimbursement amounts and each DEFENDANT acted knowingly, as defined in the False Claims Act, in providing the false and misleading representations of wholesale prices that caused the STATES to pay claims for the DEFENDANTS' drugs in excessive amounts. The wholesale prices provided by the

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DEFENDANTS were provided to cause the STATES' Medicaid Programs to pay amounts based on the information and thus constituted claims submitted to the Government.

60. False claims at issue in this action were also submitted to the STATES' Medicaid Programs by or on behalf of the pharmacies that sought and received payment in excessive amounts because of the false wholesale price representations made by the DEFENDANTS directly or indirectly to the STATES' Medicaid Programs. The specific false claims are thus each and every claim submitted to the STATES' Medicaid Programs for which the payment amount was determined by use, in whole or to any degree, of the false and misleading price representations of the DEFENDANTS. The false claims at issue number in the tens of thousands and each claim is in the possession of the individual state's Medicaid Program or fiscal agent to which it was submitted. The Relator has identified the specific false claims to the UNITED STATES by providing the truthful prices concealed from the STATES by the DEFENDANTS for each drug, providing information about the DEFENDANTS' exploitation of the States' Medicaid Programs through the use of financial inducements for the specified drugs, specific identification information about the prescription drugs, and the specific false price representations in question.

61. The damages sought herein include, but are not limited to, those arising from the false claims for the specified drugs set out in Sections 6 through 9 and elsewhere throughout this Complaint. The false claims for the specified drugs set out herein are alleged to meet the specificity and particularity requirements for pleading under the Federal Rules of Civil Procedure. The damages sought herein encompass all damages and penalties

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recoverable due to the false claim scheme of the DEFENDANTS alleged herein relating to all drugs of all sizes about which false price and cost representations or records were used in connection with, considered or made available in, caused, aided or otherwise affected the presentment, payment or approval of false claims. These claims also encompass recovery of the funds paid for false claims due to the DEFENDANTS' false drug price and cost representations, regardless of the Government program that actually expended the funds, the person or entity that ultimately received the funds or the person or entity from which the United States ultimately recovers the funds.

**b.) The DEFENDANTS each acted knowingly.**

62. The DEFENDANTS are prohibited by the False Claims Act from making false representations in connection with claims for Government funds, are required by the Food and Drug Act to report true prices and are prohibited by the Medicare and Medicaid Anti-Kickback laws from arranging financial inducements for providers.

63. The patients and the States' Medicaid Programs are not aware of the prices actually paid for the specified drugs by the pharmacies presenting the claim for payment. The DEFENDANTS concealed from the STATES' Medicaid Programs price reductions occurring due to competition in the marketplace and falsely and fraudulently represented drug prices that far exceeded the truthful prices.

64. At all times material to this action, each of the DEFENDANTS acted "knowingly" as that term is defined at 31 U.S.C. §3729(b) by:



**CIVIL ACTION NO. \_\_\_\_\_**

a) Causing the presentation of false and fraudulent claims for payment or approval by the States' Medicaid programs and

b) Making and using false statements and/or records for the purpose of getting false or fraudulent claims approved or paid by the STATES' Medicaid programs.

65. The DEFENDANTS were clearly placed on notice that their conduct would cause the STATES' Medicaid programs to pay claims for the specified drugs in amounts exceeding that permitted by applicable law, in part, because:

a) Each of the DEFENDANTS was on notice of federal statutes and regulations limiting payment of Medicaid claims for the specified drugs to an amount necessary to cover the cost of the drug.

b) Each of the DEFENDANTS was on notice that the States' Medicaid programs were not authorized or permitted by applicable law to pay claims for the specified drugs in excessive amounts.

c) Each of the DEFENDANTS was on notice that federal statutes and regulations prohibited them from making misleading representations about the specified drugs, including misleading price or cost representations.

66. Each of the DEFENDANTS was on notice that federal statutes and regulations prohibited them from making misleading representations about the specified drugs, including misleading price or cost representations:



a) Each of the DEFENDANTS is required to comply with the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 et. seq., and the regulations promulgated pursuant thereto.

b) The price and cost representations about the specified drugs constitute advertising that is included in the “labeling” provisions of the Federal Food and Drug Act and related regulations. 21 U.S.C. §§321; 352.

c) Each of the DEFENDANTS is prohibited from disseminating any information about their prices or costs of the specified drugs that is “false or misleading in any particular . . .” 21 U.S.C. §§352(a).

d) Each of the DEFENDANTS was on notice that it possessed a duty to assure that representations about prices and costs of the specified drugs were not misleading, taking into account:

“ . . . not only representations made or suggested by statement, word, design, device, or any combination thereof, but also to the extent to which the labeling or advertising fails to reveal facts material in light of such representations”

21 U.S.C. §321(a) .

e) The DEFENDANTS can and do make truthful representations of wholesale prices for most of their other drugs.

67. Each DEFENDANT was on notice that it was prohibited by federal statute from paying or causing the payment of, directly or indirectly, money or other financial benefit to induce its customers to order the specified drugs when the Medicare or States’ Medicaid Programs would be paying claims. 42 U.S.C. §1320a-7b(b)(2) and 42 U.S.C. §1395nn(a)(1)(B).

68. Notwithstanding the DEFENDANTS' knowledge that the Government relied upon the DEFENDANTS' representations of price and cost and their knowledge of the applicable statutory requirements and prohibitions, each of the DEFENDANTS repeatedly, systematically and falsely reported inflated wholesale prices as specified in Sections 6 through 9.

**c.) The DEFENDANTS directly benefitted through increased sales.**

69. The DEFENDANTS benefit directly from their false pricing scheme by maximizing their products' sales volume while capturing market share. An example of how the DEFENDANTS directly benefit from their false pricing scheme is demonstrated by data for the first quarter of 1997 from the State of Florida's Medicaid Program setting out Florida Medicaid's reimbursements paid to pharmacies for the drug Albuterol Sulfate, 0.083% Solution ("Albuterol"), by DEFENDANTS DEY and [REDACTED] and their competing manufacturers [REDACTED].

70. Albuterol is a prescription drug which is administered by inhalation and is used for the treatment of many respiratory illnesses. First quarter, 1997, reimbursement data from the State of Florida's Medicaid Program demonstrates that the wider "the Spread" between the true cost paid by providers versus the reimbursement paid by Medicaid the more a specific manufacturer's product will be utilized instead of a competitor's product. The DEFENDANTS [REDACTED] and DEY and the pharmaceutical manufacturers [REDACTED], have all made representations of Wholesale Acquisition Cost to the State of Florida as set out in the chart below. As a direct result of the false representations of prices

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and costs, the DEFENDANTS [REDACTED] and DEY caused the State of Florida's Medicaid Program to unwittingly pay more than one million dollars for the first quarter of 1997 over the reasonable reimbursement amounts which the State intended to pay. The chart further sets out the number of reimbursed claims, VEN-A-CARE's cost per ml and "the Spread" between Medicaid reimbursement and true cost. A review of the chart clearly demonstrates that the vast majority of providers utilize the manufacturer's pharmaceutical with the greatest "Spread" between the true Wholesale Acquisition Cost and the inflated false Wholesale Acquisition Cost reported by the pharmaceutical manufacturer.

**FALSE PRICING SCHEME - "THE SPREAD"**

**FLORIDA MEDICAID REIMBURSEMENT (1st Quarter 1997)  
ALBUTEROL SULFATE SOLUTION 0.083%**

Manufacturer	VAC's Cost per ml	Florida Medicaid Reimbursement per ml	The Spread	# of claims	Reimbursement paid by Florida Medicaid
[REDACTED]	\$0.09	\$0.3590	\$0.269	12,673	\$763,595.42
Dey	\$0.10	\$0.3531	\$0.2531	9,792	\$707,220.50
[REDACTED]	\$0.10	\$0.2138	\$0.1138	102	\$4,981.86
[REDACTED]	N/A	\$0.1787	**	19	\$1,278.08
TOTAL REIMBURSEMENT BY THE STATE OF FLORIDA MEDICAID PROGRAM (January 1 through March 31, 1997)					\$1,477,075.86
**	The use of the spread to falsify claims is evidenced by the fact that [REDACTED] and DEY's customers will receive a greater windfall by purchasing their product than they could if they somehow acquired the same product from [REDACTED] free of charge.				

71. The grossly inflated payments unwittingly made by the States' Medicaid Programs not only served as an inducement to providers to purchase a particular manufacturer's product but also served to drive over-utilization. The Relator, prior to filing the Complaint, surveyed three national pharmacy providers of Albuterol to determine their business practices for their sales of Albuterol to the Medicare and States' Medicaid Programs. The Relator's principals used positions in an affiliated home health care company to pose as an interested customer. The Relator determined that the payment of kickbacks and/or split fees were common place between the pharmacies and home health care companies who could provide the pharmacies with patient referrals. One marketing scheme offered by one of the pharmacies was the automatic shipping of refills of Albuterol every month without verifying continuing need with the patient or physician in order to maximize the sales of Albuterol and reimbursement.

**d. The DEFENDANTS' False Claim Scheme deprived the Government of the protection of The Federal Upper Limits ("FUL").**

72. A representative example of the DEFENDANTS' efforts to deprive the Government of the benefit of the Federal Upper Limit involves the drug [REDACTED]. In a letter dated November 7, 1996, DEFENDANT [REDACTED] made false price representations about the company's drug [REDACTED] to the State of Florida Medicaid Agency (Attached hereto as Exhibit "5" is a true and correct copy of said letter). Application of Florida's methodology of WAC plus 7%, to the prices represented by DEFENDANT [REDACTED] would have resulted in reimbursement for [REDACTED] of \$59.65

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(WAC = \$55.75 + 7% = \$59.65), plus the professional dispensing fee. However, [REDACTED] falls under the FUL program and its reimbursement was limited as of January, 1997, to \$0.0464 per 50mg tablet or \$4.64 per one hundred (100) 50mg tablets.

73. After having been alerted to the false claim scheme by the Relator, representatives of the State of Florida's Medicaid Program refused to cover DEFENDANT [REDACTED] until such time as the State received from DEFENDANT [REDACTED] what the State considered to be DEFENDANT [REDACTED] truthful prices for [REDACTED]. The fact that Florida was not covering DEFENDANT [REDACTED] led to complaints to DEFENDANT [REDACTED] from pharmacies in Florida who had dispensed DEFENDANT [REDACTED] to Florida Medicaid recipients and who were receiving denials for payment by Unisys, the State's fiscal agent.

74. Approximately one month later, a State of Florida official received a telephone call from a person who stated he represented DEFENDANT [REDACTED] and requested immediate coverage of [REDACTED]. The Florida Medicaid official stated she would not cover the drug unless she received truthful prices. The person who represented DEFENDANT [REDACTED] stated words to the effect, "What does it matter? This drug is covered by the FUL program". The Florida official stated that it did matter as it could affect not only the reimbursement amount the State paid for [REDACTED] but also, if all manufacturers followed DEFENDANT [REDACTED] course and conduct of making false pricing representations, it would cause the entire FUL program



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to be set at inflated amounts and completely frustrate the Government policy implemented by the FUL program.

75. Only when it became clear to DEFENDANT [REDACTED] representative that the Florida official was standing her ground, did DEFENDANT [REDACTED] provide a written disclosure dated December 5, 1996, of the truthful prices, (Attached hereto as Exhibit "6" is a true and exact copy of said letter). Applying Florida's Medicaid reimbursement methodology to DEFENDANT [REDACTED] truthful prices, the State pays \$4.24 for [REDACTED] (WAC  $\$3.96 + 7\% = \$4.24$ ). The truthful prices saved the U.S. Government and the State of Florida \$0.40 for each one hundred 50mg tablets.

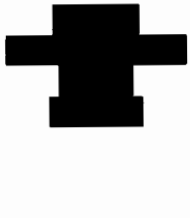
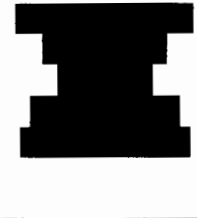
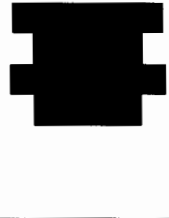


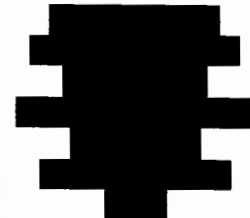









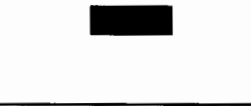






















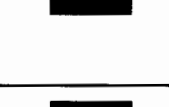







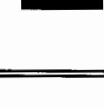

76. The persistence of the Florida Medicaid representatives curtailed DEFENDANT [REDACTED] from circumventing the protections of the FUL program and caused DEFENDANT [REDACTED] to report a truthful WAC to First Data Bank. The following table summarizes the above allegations:

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

77. The following Table illustrates reimbursements and the corresponding harm caused to the STATES' Medicaid programs as a result of DEFENDANT

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\_\_\_\_\_ false representations of wholesale prices for other drugs covered by the FUL program.

## SECTION NO. 6



78. 





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**PAGE 36 THROUGH 39  
HAVE BEEN COMPLETELY REDACTED  
which includes Paragraphs 79 and 80**

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[REDACTED]					
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

81. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**SECTION NO. 7**  
**THE SPECIFIC FALSE PRICE AND COST**  
**REPRESENTATIONS OF DEFENDANT DEY**

82. At various times from on or after April 7, 1994, and continuing through the present date, DEFENDANT DEY knowingly caused the STATES' Medicaid programs to pay

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false or fraudulent claims for drugs specified in this Section and further made or used false or fraudulent records and/or statements to get such claims paid or approved. As a result of the said actions of DEFENDANT DEY and those persons and entities acting directly or indirectly in concert with DEFENDANT DEY, the STATES' Medicaid Programs paid grossly excessive, unreasonable and unlawful amounts for claims for the drugs specified in this Section. The acts committed by DEFENDANT DEY that caused the STATES' Medicaid Programs to pay or approve said false or fraudulent claims included, but were not necessarily limited to, knowingly making false or fraudulent representations about the wholesale prices of the drugs specified in this Section which DEFENDANT DEY knew would be relied upon by the STATES' Medicaid Programs in paying or approving claims for the drugs specified in this Section. Each of said representations were material and were relied upon by the STATES' Medicaid Programs in paying or approving claims for the drugs specified in this Section.

83. DEFENDANT DEY knowingly caused its false or fraudulent wholesale price representations to be transmitted by First Data Bank's automated services and further made or used false records or statements regarding its wholesale prices and of the drugs specified in this Section and submitted same to the STATES' Medicaid Programs continuously throughout the years specified in this Section. For the purposes of specificity and particularity, the said false wholesale prices, as they are currently reflected in First Data Banks automated services, have been organized into a chart form for each drug in question and for each NDC number assigned to each drug in question. The information provided under the columns for Defendant's published wholesale price reflects the false price representations made by DEFENDANT DEY. The information under the Relator's Cost columns reflects the true price

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that DEFENDANT charged the Relator for the drug or caused another entity to charge the Relator for the drug.

DRUG STRENGTH & SIZE, NDC#s	DEY's REPORTED FALSE WACs	RELATOR'S COST (in or about March 2000)
ALBUTEROL INHALATION AEROSOL 17 gm 49502-0303-17	\$5.99	\$2.90
ALBUTEROL INHALATION AEROSOL (refill) 17 gm 49502-0303-27	\$5.74	\$2.99

84. For the purposes of specificity and particularity, the said false price and cost representations as they were submitted to the State of Texas on or after April 7, 1994 have been organized into a chart form for each drug by name, NDC Number, Texas Medicaid Payment Amount, RELATOR'S cost, the gross profit and the gross profit expressed as a percentage. The amount listed under the RELATOR'S Cost column reflects the true price that DEFENDANT DEY charged the RELATOR'S for the drug or caused another entity to charge the RELATOR'S for the drug. Accordingly, a comparison of the RELATOR'S true costs with the price and cost representations made by the DEFENDANT DEY establishes the falsity of DEY's representations for the specified drugs. The materiality of the false statements and misrepresentations of material fact is reflected in the gross profit between the true cost to the RELATOR'S and the amount paid by Texas Medicaid in reliance on information reported by DEY in that Texas Medicaid intended to pay an amount based upon estimated acquisition cost that would not include such gross profit:

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<b>DEFENDANT DEY</b>					
Drug	NDC #	<u>WEAC</u> <u>DEAC</u>	Relator's Cost (in or about March 2000)	<u>WEAC</u> Provider's Gross Profit \$ <u>DEAC</u> Provider's Gross Profit \$	<u>WEAC</u> Provider's Gross Profit % <u>DEAC</u> Provider's Gross Profit %
Albuterol 17 gm	49502-0303-17	\$0.39520/gm <u>\$6.71</u> \$0.352940/gm \$5.99	\$2.90	<u>\$3.81</u> \$3.09	<u>131%</u> 106%
Albuterol refill	49502-0303-27	\$0.378810/gm <u>\$6.44</u> \$0.338230/gm \$5.75	\$2.99	<u>\$3.45</u> \$2.76	<u>115%</u> 92%

85. As a direct and proximate result of the actions of the DEFENDANT DEY alleged herein, the United States has sustained damages recoverable under the False Claims Act, together with treble damages, penalties, attorneys' fees and costs.

**SECTION NO. 8**

[REDACTED]

86. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**PAGES 44 THROUGH 48  
HAVE BEEN COMPLETELY REDACTED  
WHICH INCLUDES PARAGRAPHS  
87 THROUGH 92**



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[REDACTED]					
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

93. [REDACTED]

[REDACTED]

[REDACTED]

**COUNT I**

**FALSE CLAIMS ACT;  
CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS**

94. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [REDACTED], DEY INC.,

[REDACTED]

[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.

95. Relator realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

**CIVIL ACTION NO. \_\_\_\_\_**

96. The DEFENDANTS from a date on or before April 7, 1994, to the present date, knowingly [as defined in 31 USC, §3729(b)] caused to be presented to officers or employees of the STATES' Medicaid Programs false or fraudulent claims [as explained in United States v. Neifert-White, 390 US 228, 232-233 (1968)] for payment or approval, in that the DEFENDANTS caused to be presented to officers or employees of the STATES' Medicaid Programs false or fraudulent price and cost information for the drugs specified herein and caused STATES' Medicaid Programs to pay out sums of money to the providers and suppliers of the DEFENDANTS' specified drugs grossly in excess of the amounts permitted by law, resulting in great financial loss to the STATES' Medicaid Programs and the UNITED STATES.

97. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars (\$10,000,000.00), all in violation of 31 U.S.C. §3729(a)(1).

**COUNT II**

**FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR STATEMENT  
TO BE MADE OR USED TO GET A FALSE OR FRAUDULENT  
CLAIM PAID OR APPROVED BY THE GOVERNMENT**

98. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [REDACTED], DEY INC.,  
[REDACTED]  
[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.

**CIVIL ACTION NO. \_\_\_\_\_**

99. Relator realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

100. The DEFENDANTS, from a date on or before April 7, 1994 to the present date, knowingly [as defined in §3729(b)] caused false records or statements to be made or used to get false or fraudulent claims [as explained in United States v. Neifert-White, 390 US 228, 232-233 (1968)] to be paid or approved by the STATES' Medicaid Programs, in that the DEFENDANTS, caused false records or statements of prices and costs of the DEFENDANTS' drugs specified herein to be used by the STATES' Medicaid Programs to pay or approve claims presented by the providers and suppliers of the DEFENDANTS' specified drugs, which claims were grossly in excess of the amounts permitted by law, resulting in great financial loss to the UNITED STATES.

101. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars (\$10,000,000.00), all in violation of 31 U.S.C. §3729(a)(2).

**COUNT III**

**FALSE CLAIMS ACT; CAUSING FALSE RECORDS OR  
STATEMENTS TO BE USED TO CONCEAL AN OBLIGATION  
TO PAY MONEY TO THE GOVERNMENT**

102. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [REDACTED], DEY INC.,

[REDACTED]

[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.

**CIVIL ACTION NO. \_\_\_\_\_**

103. Relator realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

104. The DEFENDANTS, from a date on or before April 7, 1994 to the present date, knowingly [as defined in §3729(b)] caused false records or statements to be made or used to conceal obligations to pay money to the STATES' Medicaid Programs, in that: the DEFENDANTS knew that the STATES' Medicaid Programs were using the DEFENDANTS' false price and cost representations for purposes of paying or approving claims of the providers and suppliers of the DEFENDANTS' specified drugs; the DEFENDANTS knew that sums of money paid by the UNITED STATES and STATES' Governments to the providers and suppliers of the DEFENDANTS' specified drugs were grossly in excess of the amounts permitted by law; the DEFENDANTS knew it was the obligation of the STATES' and United States' Governments to recoup governments' funds paid in excess of the amounts permitted by law; the DEFENDANTS, nevertheless, continued to cause the using and making of false records or statements of prices and costs for the specified drugs that were grossly in excess of the reasonable amounts permitted by law; and the DEFENDANTS thus concealed from the STATES' Governments an obligation of the providers and suppliers of the DEFENDANTS' specified drugs to pay recoupment monies to the STATES' Medicaid Programs, resulting in great financial loss to the UNITED STATES and STATES' Governments.

105. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars (\$10,000,000.00), all in violation of 31 U.S.C. §3729(a)(7).

CIVIL ACTION NO. \_\_\_\_\_

**COUNT IV**

**FALSE CLAIMS ACT; CAUSING PRESENTATION OF  
FALSE OR FRAUDULENT CLAIMS; ILLEGAL REMUNERATION**

106. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [REDACTED], DEY INC.,

[REDACTED]

[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.

107. Relator realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

108. The DEFENDANTS, from on or about April 7, 1994 to the present date, knew that the prices charged to their customers for the specified drugs were significantly reduced in amount from the prices and costs represented by the DEFENDANTS and upon which the DEFENDANTS knew Medicaid claims would be approved and paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from the STATES' Medicaid Programs to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified drugs for which the DEFENDANTS knew that payment would be made, in whole or in part, by the STATES' Medicaid Programs. Such financial inducement is specifically prohibited by 42 U.S.C. §1320a-7b(b)(2) and 18 U.S.C. §2.

109. The DEFENDANTS knew that the STATES' Medicaid Programs would not pay or approve claims for the specified drugs if it were disclosed to the STATES' Medicaid



**CIVIL ACTION NO. \_\_\_\_\_**

Programs that said claims were for amounts that included remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

110. The DEFENDANTS also knew that their customers, in presenting claims for the specified drugs to the STATES' Medicaid Programs, would not and did not disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

111. The DEFENDANTS' knowing and willful actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2), in causing the omission of material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused the claims for the specified drugs to be false and fraudulent claims and caused the claims to be presented to the STATES' Medicaid Programs for payment and approval in violation of 31 U.S.C. §3729(a)(1).

112. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars (10,000,000.00) all in violation of 31 U.S.C. §3729(a)(1).

**COUNT V**

**FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR  
STATEMENT TO BE MADE OR USED TO GET  
A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE  
GOVERNMENT; ILLEGAL REMUNERATION**

113. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the Defendants: [REDACTED], DEY INC.,

[REDACTED]

[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.



**CIVIL ACTION NO.** \_\_\_\_\_

114. Relator realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

115. The DEFENDANTS, from on or before April 7, 1994 to the present date, knew that the prices charged to their customers for the specified drugs were significantly reduced in amount from the prices and costs represented by the DEFENDANTS and upon which the DEFENDANTS knew Medicaid claims would be approved and paid. Accordingly, the DEFENDANTS have each knowingly offered or paid, or caused to be offered or paid, directly or indirectly, overtly or covertly, in cash or in kind, remuneration to their customers in the form of price reductions and/or in the form of illegal remuneration from the STATES' Medicaid Programs to induce them to purchase, order or arrange or to recommend purchasing, arranging or ordering the specified drugs for which the DEFENDANTS knew that payment would be made, in whole or in part, by the STATES' Medicaid Programs. Such financial inducement is specifically prohibited by 42 U.S.C. §1320a-7b(b)(2) and 18 U.S.C §2.

116. The DEFENDANTS knew that the STATES' Medicaid Programs would not pay or approve claims for the specified drugs if it were disclosed to the STATES' Medicaid Programs that said claims were for amounts that included remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

117. The DEFENDANTS also knew that their customers, in presenting claims for the specified drugs to the STATES' Medicaid Programs, would not and did not disclose that the claim amounts included the remuneration prohibited by 42 U.S.C. §1320a-7b(b)(2).

118. The DEFENDANTS' knowing and willful actions in arranging for their customers to receive remuneration prohibited by 42 U.S.C. §1320a-7b(b)2, in causing the omission of

**CIVIL ACTION NO. \_\_\_\_\_**

material information from the claims, and in causing the failure to properly disclose and appropriately reflect the remuneration in the claims, caused the claims for the specified drugs to be false records or statements that were made and used to get a false or fraudulent claim paid or approved by the Government. The DEFENDANTS' actions herein caused said false records or statements to be made and used as prohibited by 31 U.S.C. §3729(a)(2).

119. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars (\$10,000,000.00) all in violation of 31 U.S.C. §3729(a)(2).

**COUNT VI**

**FALSE CLAIMS ACT; CAUSING PRESENTATION OF  
FALSE OR FRAUDULENT CLAIMS; PROHIBITED REFERRALS,  
CLAIMS AND COMPENSATION ARRANGEMENTS**

120. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTS: [REDACTED], DEY INC.,

[REDACTED]

[REDACTED] under the False Claims Act, 31 U.S.C. §§3729-3732.

121. Relator realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

122. The DEFENDANTS, from on or before April 7, 1994 to the present date, knowingly presented or caused to be presented, prohibited claims or bills to individuals and other entities for designated health services [outpatient prescription drugs] furnished pursuant to prohibited referrals from physicians, physician groups and/or outpatient clinics with which

**CIVIL ACTION NO. \_\_\_\_\_**

the DEFENDANTS had financial relationships, for which the DEFENDANTS knew that payment would be made, in whole or in part, by the STATES' Medicaid Programs. Such prohibited referrals, claims, bills and compensation arrangements are specifically prohibited by 42 U.S.C. §1395nn(a)(1)(B) and 18 U.S.C §2.

123. The DEFENDANTS knew that the STATES' Medicaid Programs would not pay or approve claims for the outpatient prescription drugs to the STATES' Medicaid Programs that said claims were for amounts that included claims or bills prohibited by 42 U.S.C. §1395nn(a)(1)(B).

124. The DEFENDANTS knowingly presented or caused their referring physicians, physician groups and outpatient clinics to present claims or bills for the DEFENDANTS' outpatient prescription drugs to the STATES' Medicaid Programs for payment or approval that were false or fraudulent.

125. The DEFENDANTS' knowing actions in having compensation arrangements for its referring physicians, physician groups and outpatient clinics prohibited by 42 U.S.C. §1395nn(a)(1)(B) and in presenting or causing the presentment of prohibited claims in violation of 42 U.S.C. §1395nn(a)(1)(B) for payment or approval caused the claims for the outpatient prescription drugs presented to the STATES' Medicaid Programs to be false or fraudulent claims in violation of 31 U.S.C §3729(a)(1).

126. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars (\$10,000,000.00) all in violation of 31 U.S.C. §3729(a)(1).

CIVIL ACTION NO. \_\_\_\_\_

**COUNT VII**

**FALSE CLAIMS ACT; CAUSING A FALSE RECORD OR  
STATEMENT TO BE MADE OR USED TO GET  
A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE  
GOVERNMENT; PROHIBITED REFERRALS,  
CLAIMS AND COMPENSATION ARRANGEMENTS**

127. This is a civil action by the Plaintiff, UNITED STATES, and the Relator, VEN-A-CARE, on behalf of the UNITED STATES and on behalf of the Relator, against the DEFENDANTS: [REDACTED], DEY INC.,

[REDACTED]

[REDACTED], under the False Claims Act, 31 U.S.C. §§3729-3732.

128. Relator realleges and incorporates by reference paragraphs 1 through 93 as if fully set forth herein and further alleges as follows:

129. The DEFENDANTS, from on or before April 7, 1994, to the present date, knowingly presented or caused to be presented, prohibited claims or bills to individuals and other entities for designated health services [outpatient prescription drugs] furnished pursuant to prohibited referrals from physicians, physician groups and/or outpatient clinics with which the DEFENDANTS had financial relationships, for which the DEFENDANTS knew that payment would be made, in whole or in part, by the STATES' medicaid programs. Such prohibited referrals, claims, bills and compensation arrangements are specifically prohibited by 42 U.S.C. §1395nn(a)(1)(B) and 18 U.S.C §2.

130. The DEFENDANTS knew that the STATES' Medicaid Programs would not pay or approve claims for the outpatient prescription drugs if it were disclosed to the STATES'

**CIVIL ACTION NO. \_\_\_\_\_**

Medicaid Programs that said claims were for amounts that included claims or bills prohibited by 42 U.S.C. §1395nn(a)(1)(B).

131. The DEFENDANTS knowingly made or used or caused their referring physicians, physician groups or outpatient clinics to make or use false records or statements to get false or fraudulent claims and bills for the DEFENDANTS' outpatient prescription drugs to be paid or approved by the STATES' Medicaid Programs.

132. The DEFENDANTS' knowing presentment or causing others to present, claims or bills to the STATES' Medicaid Programs in violation of 42 U.S.C. §1395nn(a)(1)(B) without disclosing facts revealing said violations constituted the making or using, or the causing others to make or use, false records or statements to get false or fraudulent claims paid or approved in violation of 31 U.S.C. §3729(a)(2).

133. Because of the DEFENDANTS' conduct as set forth in this Count, the UNITED STATES suffered actual damages in excess of Ten Million Dollars (\$10,000,000.00) all in violation of 31 U.S.C. §3729(a)(2).

**REQUESTS FOR RELIEF**

WHEREFORE, the Relator, on behalf of the UNITED STATES, demands that judgment be entered in its favor and against DEFENDANTS: [REDACTED]

[REDACTED], DEY, [REDACTED]

[REDACTED], with judgment to be entered against each defendant for the amount of damages: to the UNITED STATES arising from claims for each Defendant's respective specified drugs as follows:



**CIVIL ACTION NO. \_\_\_\_\_**

1. On Count I (False Claims Act; Causing Presentation of False Claims) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false claim;

2. On Count II (False Claims Act; Causing False Statements To Be Used To Get False Claims Paid By The GOVERNMENT) for triple the amount of UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;

3. On Count III (False Claims Act; causing False Statements To Be Used To conceal An Obligation To Pay Money To The GOVERNMENT) for triple the amount of the UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false or fraudulent claim paid;

4. On Count IV (False Claims Act; Causing Presentation of False and Fraudulent Claims; Illegal Remuneration) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false claim;

5. On Count V (False Claims Act; Causing A False Record Or Statement To Be Made Or Used To Get A False Or Fraudulent Claim Paid Or Approved by the Government; Illegal Remuneration) for triple the amount of UNITED STATES' damages plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;



**CIVIL ACTION NO. \_\_\_\_\_**

6. On Count VI (False Claims Act; Causing Presentation of False or Fraudulent Claims; Prohibited Referrals, Claims and Compensation Arrangements) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;

7. On Count VII (False Claims Act; Causing a False Record or Statement to be Made or Used to get a False or Fraudulent Claim Paid or Approved by the Government; Prohibited Referrals, Claims and Compensation Arrangements) for triple the amount of the UNITED STATES' damages, plus civil penalties of no more than TEN THOUSAND DOLLARS (\$10,000.00) and no less than FIVE THOUSAND DOLLARS (\$5,000.00) for each false statement;

8. For all fees and costs of this civil action; and

9. For such other and further relief as the Court deems just and equitable.

Further, the Relator, on its behalf, requests that it receive thirty percent (30%), [twenty-five percent (25%) if the United States Government intervenes and proceeds with this case] or such other maximum amount as permitted by law, of the proceeds of this action or settlement of this action collected by the UNITED STATES, plus an amount for reasonable expenses incurred, plus reasonable attorneys' fees and costs of this action. The Relator requests that its percentage be based upon the total value recovered, including any amounts received from individuals or entities not parties to this action.

CIVIL ACTION NO. \_\_\_\_\_

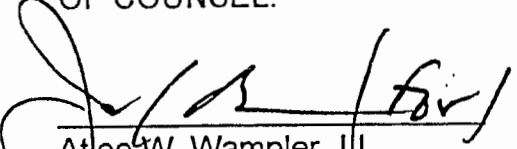
DEMAND FOR JURY TRIAL

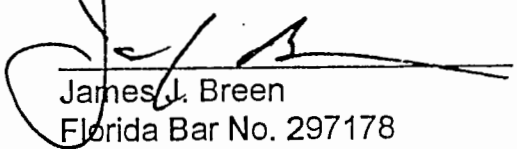
A jury trial is demanded in this case.

Respectfully submitted,  
Attorneys for  
the Private Person Plaintiff,  
Ven-A-Care of the Florida Keys, Inc.

\_\_\_\_\_  
Francis D. Dibble, Jr.  
BBO No.: 123220  
Katherine A. Robertson  
BBO No. 557609  
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OF COUNSEL:

  
\_\_\_\_\_  
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Florida Bar No. 311227

  
\_\_\_\_\_  
James J. Breen  
Florida Bar No. 297178  
Attorneys for the United States  
of America by and through  
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Keys, Inc., the Relator  
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Miami, Florida 33131  
Telephone: (305)577-0044  
Facsimile: (305)577-8545

CIVIL ACTION NO. \_\_\_\_\_

CERTIFICATE OF SERVICE

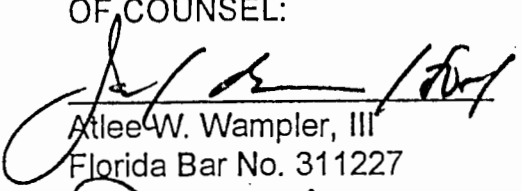
I HEREBY CERTIFY that on this 10<sup>th</sup> day of April, 2000, I caused an original and a copy of this Complaint to be filed under seal and in camera for sixty (60) days and not to be served on the Defendants named herein or until further order of this Honorable Court.

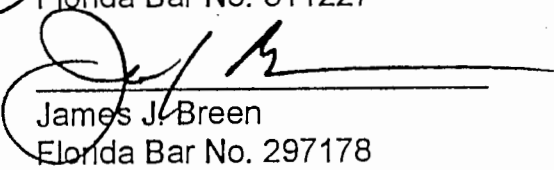
I HEREBY CERTIFY that prior to this 10<sup>th</sup> day of April, 2000, I caused a copy of this Complaint and written disclosure of substantially all material evidence and information the Relator, VEN-A-CARE possesses to be served on the Government pursuant to Rule 4(i)(1)(A) and (B), Fed.R.Civ.P., prior to the filing of this Complaint by delivering a copy of the Summons, Complaint, material evidence and information to the United States Attorney for the District of Massachusetts, and by sending a copy of the Summons, Complaint, material evidence and information by Certified Mail, Return Receipt Requested, to the Attorney General of the United States in Washington, D.C.

Respectfully submitted,

\_\_\_\_\_  
Francis D. Dibble, Jr.  
BBO No.: 123220  
Katherine A. Robertson  
BBO No. 557609

OF COUNSEL:

  
Atlee W. Wampler, III  
Florida Bar No. 311227

  
James J. Breen  
Florida Bar No. 297178

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TO: WBB

AT: 13055778545

**Texas Department of Health**

William R. Archer III, M.D.  
Commissioner of Health

<http://www.tdh.state.tx.us>

1100 West 49th Street  
Austin, Texas 78756-3199  
(512) 438-7111

Patti J. Patterson, M.D., M.P.H.  
Executive Deputy Commissioner

Under the Omnibus Budget Reconciliation Act (OBRA) of 1990, the state of Texas Vendor Drug Program will continue to request completed questionnaire as a requirement for the production addition to the Texas Vendor Drug Index (TVDI). A form is included so that all necessary information from the manufacturer will be available for pricing and dosing recommendations. Questionnaires should be limited to no more than 20 per submittal request for any one month period. A separate questionnaire is to be submitted for each drug and strength. Please supply a cover sheet listing all products, strengths and package sizes for which you are submitting applications. Questions must be answered in full (NO - N/A). This form may be reproduced.

All inquiries regarding this questionnaire for BYD and revisions are to be directed to:

Texas Department of Health  
Bureau Vendor Drug  
1100 West 49th Street  
Austin, Texas 78756-3174

Drugs are listed in the BVD using the NDC number of the manufacturer or distributor who is holding the drug forth as his own and has his company's name on the label of the container that is sold to the pharmacy. If your company has a product to which the "New Drug Coverage" applies, please add the FDA approval date of the New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug Approval (ADA) to the questionnaire.

Martha McNeill, R.Ph.  
Director of Product Management  
Bureau of Vendor Drug  
(512)338-6965  
(512)338-6462-Fax  
(512)338-6932-Secretary

**EXHIBIT "1"**

REQUEST FOR INFORMATION FOR NEW DRUG PRODUCT OR FOR  
 ADDITIONAL INFORMATION OF PRODUCTS CURRENTLY  
 INCLUDED IN TEXAS MEDICAID

Please fill out the following information for consideration on Texas Medicaid

INCLUDE A COPY OF FILE CARD, PACKAGE INSERT AND OR MATERIAL FOR PHYSICIANS

DRUG DESCRIPTION

DC. NO:	PACKAGE QTY:		
multiple package size of same strength	products may be included)		
PRODUCT BRAND NAME:			
GENERIC NAME:			
*STRUCTURALLY RELATED DRUGS:			
DRUG STRENGTH:			
COLOR:	FLAVOR:	ORANGE BOOK RATING:	
DOSEAGE FORM:	IS THIS DRUG LEGEND OR OTC?	DEA SCHEDULE OF THE DRUG:	
MAXIMUM DAILY DOSE:			
RECOMMENDED DAILY DOSE:			
INGREDIENTS/DESCRIPTION:			
*LIST SHELF LIFE:			
*ESTIMATED AVG. DURATION OF THERAPY:			
*MAXIMUM DURATION OF TREATMENT:			
<p>A - Drug products that FDA considers to be therapeutically equivalent to other                      pharmaceutically equivalent products.</p> <p>B - Drug products that FDA at this time, considers not to be therapeutically equivalent to                      other pharmaceutically equivalent products.</p> <p>C - Not listed in Orange Book</p>			

\*\* NEW ADDITIONAL INFORMATION - revised (April 1, 1998)



ATTACH COPIES OF PRICE LIST & ADD TO MAILING LIST IF NOT CURRENTLY LISTED\*\*

### PRICE INFORMATION

AVERAGE OF SUGGESTED WHOLESALE PRICE TO PHARMACY (AWP)	\$
PRICE TO WHOLESALER AND/OR DISTRIBUTOR	\$
NET PRICE TO PHARMACY	\$
PRICE TO CHAIN WAREHOUSE	\$
INSTITUTIONAL OR OTHER CONTRACT PRICE** (Nursing Home, Home Health Care)	\$
OTHER PRICE	\$

A single set of price lists is sufficient for multiple submittals.

Notes: If prices vary by specific contract or customer arrangement, you may provide a price range.\*\*

Please circle the companies to whom you report pricing information.

FAST DATA BANK PRICE ALERT

RED BOOK

EDI-SPAN

BLUE BOOK

OTHER: \_\_\_\_\_

Do you sell to distributors, repackagers, or relabelers, other than full-service drug wholesalers, who in turn sell your product to the retail trade bearing your NDC number?

If yes, attach a listing.

Attach a copy of your sales agreement with retail pharmacists (contract, policy, etc)

Attach a copy of your Vendor Liability Insurance:

- a. Included or
- b. Previously submitted or unchanged. (Do not need to resubmit)

Available date through WHOLESALERS \_\_\_\_\_



Name of firm:		
Address:		
City:	State:	Zip:
Name and address of Manufacturer of drug:		
City:	State:	Zip:
Name and Address of representatives/government affairs persons covering the Texas area; if applicable:		
City:	State:	Zip:
Phone:		

Is this product now marketed under an approved NDA or ANDA?

Submit a copy of the FDA letter of approval of the NDA or ANDA, or, if not applicable, a copy of the FDA letter of approval for marketing.

Please circle DESI classification of this product.

- 2 Non-DESI/IRS: safe and effective
- 3 DESI/IRS under review
- 4 LTE DESI/IRS for some indications
- 5 Non-Covered - LTE DESI/IRS for all indications
- 6 Non-Covered - LTE DESI/IRS withdrawn from the market

Product added to the Texas Vendor Drug Program must bear the labeler code, as defined by the FDA, of the company, with the exception of a bonafide full-service drug wholesaler, marketing the final sale to the provider.

Manufacturers or distributors having one or more of their pharmaceuticals included in the program are responsible for submitting notification of any changes pertaining to any of the above information not later than such revisions scheduled to occur to:

Texas Department of Health  
Bureau of Vendor Drug  
Attn: Martha McNeill, R.Ph.  
Director of Product Management  
1100 West 49th Street  
Austin, Texas 78756-3174

I certify that the information submitted is correct to the best of my knowledge and that this product is not now in violation of either Federal or State Law. I also agree to inform the Texas Department of Health, in writing, of any changes in formulation, product status, price or availability as herein describe, within fifteen (15) days of such change.

Responsible Person (Type or Print)

Signature

Address City State Zip

Company Name

( )  
Telephone

**Point-of-Care Knowledge Bases****First DataBank**

# New Product Submission Form

For your convenience, you may use this form to add products to the National Drug Data File (NDDF). Please make copies of this form for each add.

NDC Number	
UPC Number	
Product Name	
RX or OTC	
Package Size (ml, gm, each)	
Dosage Form (tablet, capsule, powder filled vial, ampul, ointment, etc..)	
Wholesale (Distributor) Price	
Direct Price	
AWP Price	
Effective Date (start ship date)	
Active Ingredients & strengths (Package Insert and Label are preferred.)	

Company Name: \_\_\_\_\_

Your Name: \_\_\_\_\_

Telephone: \_\_\_\_\_

The Hearst Corporation, 1111 Bayhill Drive, San Bruno, California 94066 Tel: (415)588-5454 Fax: (425)588-6867

EXHIBIT "2"

**EXHIBIT "3" THROUGH EXHIBIT "6"**  
**HAVE BEEN COMPLETELY REDACTED**